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Accredited Facilities Bylaw

(Under Section 183 of *The Regulated Health Professions Act*)

The College of Physicians and Surgeons of Manitoba

(Enacted by the Councillors of the College of Physicians and Surgeons of Manitoba on November 22, 2018 repealing and replacing Bylaw #3 and 3D under The Medical Act)

Effective Date January 1, 2019
With revisions up to and including September 25, 2024

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Preamble

Prior to making this Bylaw, the Minister must be provided with a copy of the proposed Bylaw for review and Council must review and consider any comments made, pursuant to s. 183 of the RHPA.

PART A – DIAGNOSTIC FACILITIES

Article 1 – Definitions

1.1. In Part A of Bylaw:

1.1.1. "**accreditation**" means a review process conducted by CPSM to determine whether the facility being reviewed meets the standards specified by CPSM.

1.1.2. **"anatomic pathology laboratory"** means a place where human surgical tissue biopsies and specimens, cytological specimens and autopsies are examined for diagnostic purposes.

1.1.3. **"certificate of accreditation"** means a certificate issued under this Part of the Bylaw.

1.1.4. **"clinical pathology laboratory"** means a place where diagnostic testing is performed on human samples including the disciplines of chemistry, hematology, transfusion medicine, cytology, immunology, microbiology, virology, histology or pathology.

1.1.5. **"Committee"** means the Program Review Committee of CPSM.

1.1.6. **"diagnostic imaging facility"** means a place where imaging techniques are used for diagnostic purposes including radiography, ultrasound, computed tomography, magnetic resonance imaging, fluoroscopy, mammography or nuclear medicine.

1.1.7. **"facility"** means a place or a vehicle, whether privately owned or affiliated with or administered by a hospital or other health facility, which is principally equipped to perform a procedure normally performed in an anatomic pathology laboratory, a clinical pathology laboratory, a diagnostic imaging facility, or a patient service centre. A clinical pathology laboratory facility may be comprised of a primary location, which is its laboratory, and one or more patient service centres.

1.1.8. **"Facility Director"** means a physician appointed as director of a facility in accordance with this Part of the Bylaw and whose credentials are acceptable to the Committee and is synonymous with the term "medical director" used in section 183(3) of the RHPA.

1.1.9. **"patient service centre"** means a location for the collection and/or testing of specimens of blood and of body fluids for the purpose of testing in an accredited laboratory.

1.1.10. **"physician office laboratory"** means a physician's office where specimens are collected and tested by the physician or a laboratory technician/assistant qualified by training from an accredited medical laboratory technician/assistant training program and is certified or eligible for certification with the Canadian Society of Medical Laboratory Science for the diagnosis of the physician's own patients.

1.1.11. **"Standards"** means the Standards approved by the Committee for facilities.

1.1.12. **"vehicle"** means a device in, upon or by which diagnostic equipment is transported upon a roadway and which is:

1.1.12.i. used primarily for the purpose of offering diagnostic services; and

1.1.12.ii. has the approval of the Government of Manitoba to offer diagnostic services in Manitoba but does not include an emergency vehicle as defined in *The Highway Traffic Act*.

1.2. In this Bylaw, words and phrases defined in *The RHPA* have the same meaning as in the *RHPA*.

Article 2 – Application of this Part

Part A of this Bylaw applies as follows:

2.1. Pursuant to *The Regulated Health Professions Act (RHPA),* ss 183(1)[1], to all diagnostic facilities in Manitoba which are principally equipped to perform a procedure normally performed in an anatomic pathology laboratory, clinical pathology laboratory, diagnostic imaging facility, and patient service centre, in which services are performed by registrants of CPSM, other than those under the jurisdiction of the provincial or municipal governments and those designated as hospitals under *The Health Services Insurance Act,* and a facility or class of facilities exempted by Regulation from the application of s.183(1) of the *RHPA*.

[1] 183(1) This section applies to any facility in which a member performs or causes to be performed diagnostic or treatment services, such as a non-hospital medical or surgical facility or a nuclear medicine facility, other than

(a) a facility that is designated as a hospital under *The Health Services Insurance Act*;

(b) a hospital or health care facility operated by the government, the government of Canada or a municipal government; and

(c) a facility or class of facility exempted by regulation from the application of this section.

2.2. Pursuant to *s.183(15)*[2] *of the RHPA* and pursuant to the Service Purchase Agreement made between the College of Physicians and Surgeons of Manitoba and the Government of Manitoba governing diagnostic facilities, to those diagnostic facilities falling within the jurisdiction of the Government of Manitoba as specified in the Service Purchase Agreement.

2.3. Pursuant to s.12.3(1) (d) of the *CPSM General Regulation* this does not apply to a facility operated by the Canadian Blood Services, CancerCare Manitoba, St. Amant Inc., or Mount Carmel Clinic unless it is part of the Service Purchase Agreement referred to above.

Article 3 – Facility Accreditation

3.1. A facility is required to obtain accreditation before it offers any services to the public.

3.2. Accreditation of a facility must be:
- 3.2.1. except in the case of a vehicle, for a specific address or addresses.
- 3.2.2. for the fixed period of time determined by the Committee, to a maximum of 5 years.
- 3.2.3. for the procedures specified with the certificate of accreditation.

3.3. In the case of a vehicle, the facility must provide a current mailing address for the owner and the operator of the service.

3.4. Prerequisites to full accreditation of a facility pursuant to this By-law are:
- 3.4.1. compliance with the relevant standards; and
- 3.4.2. appointment of a Facility Director acceptable to the Committee.

3.5. The Committee must establish and make available on request:
- 3.5.1. Operational/technical standards for each type of facility.
- 3.5.2. the accreditation process for each type of facility.
- 3.5.3. the Committee's policies governing the accreditation process for each type of facility.

3.6. Applications for accreditation of a facility must be made to the Committee by the Facility Director, on the forms prescribed by the Committee, and must contain the information required by the Committee.

[2] 183(15) The council may enter into agreements with the government, the government of Canada or a municipal government to make this section applicable to any facility or any part of a facility that falls within that government's jurisdiction.

Accreditation Process

3.7. The accreditation process will include:
- 3.7.1 completion of a pre-inspection questionnaire by the Facility Director;
- 3.7.2 an inspection by one or more persons, with knowledge in the facility's work, designated by the Committee;
- 3.7.3 review of the facility's compliance with standards;

3.8. On completion of the accreditation process, the Committee may:
- 3.8.1 grant full accreditation and issue a certificate of accreditation to a facility if the Committee is satisfied that the facility has met all the requirements of Part A of this Bylaw and there are no identified deficiencies;
- 3.8.2 grant conditional accreditation to a facility with identified deficiencies and specifying the date it will expire if the identified deficiencies are not corrected;
- 3.8.3 deny accreditation pending correction of identified deficiencies in accordance with s. 183(7) of the RHPA; or
- 3.8.4 withdraw any existing accreditation.

3.9. Where an inspection is conducted as part of the accreditation process, and deficiencies are observed, the Committee must issue a report of the inspection and must provide a copy of the report to the applicant.

Full Accreditation

3.10. Where a facility fully complies with the relevant standards, the Committee will grant full accreditation and will specify with the certificate of accreditation the procedures for which the facility is accredited.

Accreditation Not Granted

3.11. Where accreditation is not granted, the Committee must provide written notice of its decision and the reasons therefor and information on the right of appeal to the Executive Committee.

Conditional Accreditation

3.12. Where a facility does not fully comply with the relevant standards, but the Committee is of the opinion that it is in the public interest to permit the facility to operate while it corrects specified deficiencies, the Committee may grant conditional accreditation.

3.13. Where conditional accreditation is granted, the Committee must:
- 3.13.1. provide written notice of its decision and the reasons therefor and the information on the right of appeal to the Executive Committee.

3.13.2. state in its decision a fixed deadline for the facility to comply with all relevant standards and for the Facility Director to provide written confirmation of compliance to the Committee.

3.13.3. state in its decision whether a follow-up inspection must occur before full accreditation may be granted.

3.14. The Committee may extend the deadline for compliance with standards if, in its sole discretion, the Committee deems it appropriate to do so.

3.15. Where a facility with conditional accreditation has not complied with the conditions of accreditation within the time frame fixed by the Committee, the Committee may:

3.15.1. Extend conditional accreditation

3.15.2. direct an inspection.

3.15.3. withdraw the conditional accreditation and if the facility is publicly owned, report the matter to government with the request that the government require the facility to cease operation.

3.16. If the Committee is of the opinion that the facility is unsafe, it must request the Registrar to notify the public of the deficiencies and prohibit registrants from using the facility.

Accreditation Status Review

3.17. Accreditation status may be reviewed at the discretion of the Committee.

Temporary Accreditation

3.18. Temporary accreditation may be granted for the continued operation of a facility, if the facility is already accredited, in circumstances which the Committee deems appropriate, pending the completion of the re-accreditation process.

Role of Facility Director During Accreditation

3.19. Facility Director and personnel who are subject to the accreditation process must cooperate fully, which includes but is not limited to:

3.19.1. permitting inspectors to enter the facility and inspect the premises and all diagnostic equipment located therein.

3.19.2. permitting inspectors to inspect all records pertaining to the provision of services and providing copies of the same if so requested.

3.19.3. providing requested samples or copies of any material, specimen, radiological image or product originating from the diagnostic service.

3.19.4. answering questions posed by the inspectors as to the procedures or standards of performance relating to examinations/procedures performed.

Article 4 – Maintenance of Accreditation

4.1. In order to maintain accreditation, a facility must:
- 4.1.1. comply with the relevant standards.
- 4.1.2. perform only the procedures permitted pursuant to the facility's certificate of accreditation.
- 4.1.3. at all reasonable times, be open for investigation and inspection by the Committee, with or without notice of the Committee's intention to inspect.
- 4.1.4. cooperate with and participate in the inspection process approved by the Committee for its type of facility.

4.2. During the currency of a full or conditional accreditation the Committee may direct an inspection for the purpose of monitoring compliance, if the Committee is of the opinion that:
- 4.2.1. a facility may not meet the relevant standards and
- 4.2.2. an inspection would be in the public's best interest.

Article 5 – Renewal of Accreditation

5.1. In order to renew accreditation, a facility must re-apply for accreditation at least six months prior to the expiration date of the existing accreditation.

Article 6 – Variance or Withdrawal of Accreditation

6.1 A facility may apply at any time to vary its accreditation.

6.2 If the Committee is of the opinion that the facility may be unsafe, the Committee must review the facility's accreditation and may take such steps with respect to the facility's accreditation as the Committee deems appropriate in the circumstances, including withdrawing accreditation and if the facility is publicly owned, report the matter to government with the recommendation that the government require the facility to cease operation. If the Committee is of the opinion that the facility is unsafe, it must request the Registrar to notify the public of the deficiencies and prohibit registrants from using the facility.

6.3 Where a facility is no longer providing patient services, the Committee may withdraw the facility's accreditation

6.4 Council may withdraw accreditation in accordance with the RHPA

Article 7 – Facility Director

7.1. A facility must have a Facility Director.

7.2. A Facility Director must be a physician whose credentials are acceptable to the Committee.

7.3. The Committee must establish and make available on request the qualifications for Facility Directors in each type of facility.

7.4. The Facility Director is responsible for granting privileges to any physician who wishes to work for the facility and notifying the Committee of the physicians who are granted privileges. Before granting privileges to any physician a Facility Director must:

- 7.4.1. define in writing the qualifications and competencies required in order to obtain privileges in each field of practice.
- 7.4.2. obtain written confirmation that the applicant is registered and licensed to practice medicine in Manitoba.
- 7.4.3. obtain full particulars of the applicant's education, training, competencies and experience.
- 7.4.4. take reasonable steps to ensure that the applicant has the education, training competencies and experience required, and that the applicant is otherwise a suitable candidate for privileges.

7.5. Within one year of first granting privileges to a physician, the Facility Director must review that physician's privileges. Thereafter, privileges must be reviewed by the Facility Director at least every two years.

7.6. Before granting renewal of privileges or extending the existing privileges of any physician, the Facility Director must take reasonable steps to ensure that the physician has the education, training, competencies and experience required for each field of practice for which he or she is seeking privileges within the facility.

7.7. The Facility Director must have effective control of and be responsible for the safe operation and administration of the facility, the supervision of all professional, technical and administrative activities of the facility, and for compliance with this Bylaw and with the relevant standards established by the Committee.

7.8. Without limiting the generality of the foregoing, the Facility Director must:

- 7.8.1. have access to all records and documents relating to the operation of the facility and the procedures performed therein.
- 7.8.2. communicate with any facility under his/her direction a minimum of once per year.
- 7.8.3. ensure that quality management system requirements and improvement programs are in place.

7.8.4. ensure that the facility has current up to date policies and manuals as required by the standards for that facility.

7.8.5. ensure that complete and accurate patient records and documentation relating to the operation of the facility and procedures performed are kept.

7.8.6. ensure that no procedure is carried out in the facility unless it is permitted by the certificate of accreditation.

7.8.7. ensure that technologists have the qualifications as provided by training from an accredited:

7.8.7.i. medical laboratory training program and are certified or eligible for certification with the Canadian Society of Medical Laboratory Science.

7.8.7.ii. medical radiology technology training program and are certified or eligible for certification with the Canadian Association of Medical Radiology Technologists.

7.8.8. ensure that medical laboratory technologists who are required to perform x-ray examinations and medical radiology technologists who are required to perform laboratory testing have graduated from a cross-training program.

7.8.9. ensure that laboratory technicians/assistants have the qualifications as provided by training from an accredited medical laboratory technician/assistant training program and are certified or eligible for certification with the Canadian Society of Medical Laboratory Science.

7.8.10. ensure that persons who provide services to the facility maintain competence to perform the procedures for which the facility is accredited.

7.8.11. ensure that work referred out of the facility is performed by persons with appropriate qualifications and competence to perform the work.

7.8.12. promptly notify CPSM of any change in the ownership or directorship of the facility.

7.8.13. promptly notify CPSM if the facility is no longer providing patient services.

7.8.14. where applicable, be available for consultation with referring physicians.

7.8.15. promptly notify the Committee if there is a major change in the following:

7.8.15.i. equipment.

7.8.15.ii. the accredited list of diagnostic imaging examinations, laboratory or transfusion medicine tests, or blood and blood products dispensed.

7.8.16. ensure that the duties and responsibilities of all personnel are written and understood;

7.8.17. ensure adequate quality assurance and improvement programs are in place

7.9. The Facility Director must submit to CPSM such information as required by the Committee.

Article 8 – Appeal

8.1. The facility or a registrant may appeal any decision of the Committee to the Executive Committee pursuant to sections 183 and 38 of the RHPA by filing a written notice of appeal with the Registrar within thirty calendar days of being informed of the decision. The notice of appeal must specify the reasons for the appeal.

Article 9 – Fees

9.1. A privately-owned facility shall pay all expenses, charges and fees incurred by CPSM in respect of the accreditation or inspection of the facility and the administration of Part A of this Bylaw.

Article 10 – Physician Office Laboratory

10.1. Physicians must not operate a physician office laboratory without first obtaining the written approval of CPSM.

10.2. The Committee may direct the inspection of any facility where physician office laboratory procedures are performed.

Article 11 – Transition

11.1. A facility that holds accreditation at the time this Bylaw comes into force continues to hold that accreditation status under this Bylaw in accordance with the terms of that accreditation.

11.2. A facility which has not undergone the accreditation process will be notified in writing by CPSM that it is exempt from the requirement of accreditation set forth in this Bylaw until the inspection process for that facility is complete and a report is issued, but the facility must cooperate with CPSM for the timely completion of its accreditation process in accordance with this Bylaw.

11.3. A physician who holds a Facility Directorship at the time this Bylaw comes into force continues to hold that status under this Bylaw.

PART B – NON-HOSPITAL MEDICAL OR SURGICAL FACILITIES

Article 12 – Definitions

12.1. In Part B of this Bylaw:

“accreditation” means a review process conducted by CPSM to determine whether the facility being reviewed meets the requirements specified by CPSM.

"certificate of accreditation" means a certificate issued under this Part of the Bylaw.

"Committee" means the Program Review Committee of CPSM.

“direct or indirect financial interest” means any interest owned by a registrant, by individuals connected by blood relationship, marriage or adoption to a registrant, by any corporation, proprietorship, partnership, society, business, association, joint venture, group or syndicate in which a registrant or any individual connected by blood relationship, marriage or adoption to a registrant have any interest.

"facility" means a non-hospital medical or surgical facility for the purposes of Part B of this Bylaw.

“general anaesthesia” means a controlled state of unconsciousness accompanied by partial or complete loss of protective reflexes, including inability to maintain an airway independently, or to respond purposefully to physical stimulation or verbal command, produced by pharmacologic or non-pharmacologic methods, alone or in combination.

“hospital” means a hospital under *The Hospitals Act* or the *Regional Health Authorities (Health System Governance and Accountability) Act* when proclaimed with an operational Emergency or Urgent Care Department.

"medical director" means a physician appointed as director of a facility in accordance with this Part of the Bylaw and whose credentials are acceptable to the Committee and is synonymous with the term “medical director” used in section 183(3) of the RHPA.

“**oral sedation**” means an altered state or depressed state of awareness or perception of pain brought about by pharmacologic agents and with is accompanied by varying degrees of depression of respiration and protective reflexes in which verbal contact with the patient can be maintained. This is specific to the use of oral medication alone. An example may include oral dosing of opioids and/or benzodiazepines that produce the above states.

"privileges" means the authority to admit and treat patients at a facility.

"procedural sedation" means an altered or depressed state of awareness or perception of pain brought about by pharmacologic agents and which is accompanied by varying degrees of depression of respiration and protective reflexes in which verbal contact with the patient can be maintained, and

i. includes, but is not limited to, the use of any IV or intra-muscular agent for this purpose; and
ii. requires the monitoring of vital signs,

but does not include the use of oral pre-medication alone or in combination with local anaesthesia. No distinction is made between light and deep procedural sedation for credentialing or monitoring purposes.

"procedure" means the diagnostic and treatment procedures, both medical and surgical, as approved by the Committee to be carried out in a facility.

Article 13 – Application of this Part – Procedures Requiring Accreditation

13.1. Part B of this Bylaw applies to all non-hospital medical or surgical facilities, subject to section 183 of the RHPA, and not included in Part A of this Bylaw. All non-hospital medical or surgical facilities in which procedures that have a sufficient risk of potential harm to a patient must apply for, obtain, and maintain accreditation from CPSM prior to providing any such diagnostic or treatment services or procedures.

13.2. The criteria for assessing sufficient risk of potential harm to a patient include:
- 13.2.1. Level of anaesthesia and/or sedation
- 13.2.2. Need for medical device reprocessing (infection risk)
- 13.2.3. Complexity of procedure and risk of complications

13.3. The following procedures have a sufficient risk of potential harm to the patient to require accreditation:
- 13.3.1. Any procedure that is carried out or should be carried out in accordance with generally accepted standards of care with the concurrent use of procedural or oral sedation including for patient comfort (pain and/or anxiety); See definitions of procedural and oral sedation in Article 12.
- 13.3.2. Any procedure that requires general anaesthesia, See definition of general anaesthesia; or
- 13.3.3. Procedures involving:
  - 13.3.3.i. deep, major, and complicated procedures that may require more resources than are commonly available in a medical office. Surgeons should make decisions as to the appropriate location for these surgical procedures in accordance with the resources necessary for unexpected complications and with generally accepted standards of care. These procedures may include:

13.3.3.i.a. resection of a deep, major or complicated lesion;
13.3.3.i.b. surgical and diagnostic procedures with risk of bleeding from major vessels, gas embolism, perforation of internal organs, and other life-threatening complications or requiring sterile precautions to prevent blood borne deep closed cavity or implant-related infections;

13.3.3.ii. flexible endoscopic evaluation of the gastrointestinal or genitourinary tract;
13.3.3.iii. assisted reproduction technology, uterine evacuation procedures, and hysteroscopy;
13.3.3.iv. the following Ophthalmological Procedures:
13.3.3.iv.a. cataract surgical procedures
13.3.3.iv.b. corneal laser procedures
13.3.3.iv.c. retinal procedures limited to scleral buckling and vitrectomies
13.3.3.iv.d. Lasik therapeutic procedures
13.3.3.v. the use of drugs by injection which are intended or may induce a major nerve block or spinal, epidural or intravenous regional block;
13.3.3.vi. liposuction procedures;
13.3.3.vii. hair transplantation;
13.3.3.viii. venous sclerotherapy;
13.3.3.ix. hyperbaric oxygen therapy;
13.3.3.x. hemodialysis;
13.3.3.xi. intravenous Ketamine administration;
13.3.3.xii. MDMA (3,4-methylenedioxymethamphetamine); or

13.4. CPSM registrants providing anaesthesiology services for dental procedures undertaken by members of the Manitoba Dental Association in dental surgery clinics, must comply with the Pharmacologic Behaviour Management Bylaw of the Manitoba Dental Association.
13.4.1. In addition to complying with the Pharmacologic Behaviour Management Bylaw of the Manitoba Dental Association, CPSM registrants providing these services must notify the Assistant Registrar within one working day of becoming aware of any major adverse patient outcome resulting from the anesthesiology services provided in the dental surgery clinic.

13.5. This Part of the Bylaw does not apply to any hospital or health care facility operated by a health authority or the Governments of Canada, Manitoba, or any municipality.

Article 14 – Registrants Must not Work in Non-Accredited Facilities

14.1. A registrant must not perform or cause to be performed any procedure in a facility that requires accreditation under this Part, but is not accredited, in accordance with s. 183(14) of the RHPA and in accordance with the transition provisions in Article 29.

14.2. A facility is required to obtain accreditation before it offers any services to the public.

Article 15 – Facility Accreditation

15.1 The medical director of a facility seeking accreditation must apply on the form prescribed by the Committee, specifying the procedures for which accreditation is sought.

15.2 The medical director must agree to pay the fee charged for the inspection and accreditation process even if the accreditation is not completed or granted.

Accreditation Process

15.3 The accreditation process will include:
- 15.3.1 completion of a pre-inspection questionnaire by the medical director;
- 15.3.2 an inspection by one or more registrants, with expertise in the appropriate area of medical practice, designated by the Committee;
- 15.3.3 review of the facility's compliance with requirements including CPSM and medical or other standards; and
- 15.3.4 CPSM providing the Minister with a copy of each application and report as required by section 183(17) of the RHPA.

15.4 On completion of the accreditation process, the Committee may:
- 15.4.1 grant full accreditation and issue a certificate of accreditation to a facility if the Committee is satisfied that the facility has met all of the requirements of Part B of this Bylaw and there are no identified deficiencies;
- 15.4.2 grant conditional accreditation to a facility with identified deficiencies and specifying the date it will expire if the identified deficiencies are not corrected;
- 15.4.3 not grant accreditation pending correction of identified deficiencies in accordance with s. 183(7) of the RHPA; or
- 15.4.4 withdraw any existing accreditation.

15.5 Where an inspection is conducted as part of the accreditation process, and deficiencies are observed, the Committee must issue a report of the inspection and must provide a copy of the report to the applicant.

Full Accreditation

15.6 Where a facility fully complies with the relevant requirements, the Committee will grant full accreditation and will specify with the certificate of accreditation the procedures for which the facility is accredited.

Accreditation Not Granted

15.7 Where accreditation is not granted, the Committee must provide written notice of its decision and the reasons therefor and information on the right of appeal to the Executive Committee.

Conditional Accreditation

15.8 In circumstances where a facility does not comply fully with all requirements for accreditation, and if the Committee deems it adequate for patient safety, conditional approval may be granted for the operation of a facility pending the completion of the accreditation process or while it corrects specified deficiencies.

15.9 Where conditional accreditation is granted, the Committee must:

15.9.1 provide written notice of its decision and the reasons therefor and the information on the right of appeal to the Executive Committee.

15.9.2 state in its decision a fixed deadline for the facility to comply with all relevant standards and for the medical director to provide written confirmation of compliance to the Committee.

15.9.3 state in its decision whether a follow-up inspection must occur before full accreditation may be granted.

15.10 Where conditional accreditation is granted, the medical director must provide a written response to each deficiency within the time specified by the Committee, and a follow-up inspection may occur, if the Committee so directs. Full accreditation will only be granted when identified deficiencies have been corrected to the satisfaction of the Committee.

15.11 The Committee may extend the deadline for compliance with requirements if, in its sole discretion, the Committee deems it appropriate to do so.

15.12 Where a facility with conditional accreditation has not complied with the conditions of accreditation within the time frame fixed by the Committee, the Committee may:

15.12.1 extend conditional accreditation;

15.12.2 direct an inspection;

15.12.3 withdraw the conditional accreditations.

Temporary Accreditation

15.13 Temporary accreditation may be granted for the continued operation of a facility, if the facility is already accredited, in circumstances which the Committee deems appropriate, pending the completion of the re-accreditation process.

Term of Accreditation and Renewal

15.14 Accreditation of a facility must be for the fixed period of time determined by the Committee, to a maximum of five years.

15.15 In order to renew accreditation, a facility must re-apply for accreditation at least six months prior to the expiration date of the existing accreditation. The re-accreditation process will follow the same procedure as required for accreditation. Where an application to renew is pending, the Committee may continue the facility's accreditation until a decision is made on the renewal application.

Article 16 – Maintenance of Accreditation

16.1 In order to maintain accreditation, a facility must:

- 16.1.1 comply with the relevant requirements;
- 16.1.2 perform only the procedures permitted pursuant to the facility's certificate of accreditation;
- 16.1.3 at all reasonable times, be open for investigation and inspection by the Committee, with or without notice of the Committee's intention to inspect; and
- 16.1.4 cooperate with and participate in the inspection process approved by the Committee for its type of facility.

16.2 During the currency of a full or conditional accreditation the Committee may direct an inspection for the purpose of monitoring compliance, if the Committee is of the opinion that:

- 16.2.1 a facility may not meet the requirements, standards of practice, or other standards for public safety and.
- 16.2.2 an inspection would be in the public's best interest.

Article 17 – Renewal of Accreditation

17.1 In order to renew accreditation, a facility must re-apply for accreditation at least six months prior to the expiration date of the existing accreditation.

Article 18 – Variance or Withdrawal of Accreditation

18.1. A facility may apply at any time to vary its accreditation.

18.2. If the Committee is of the opinion that the facility may be unsafe, the Committee must review the facility's accreditation and may take such steps with respect to the facility's accreditation as the Committee deems appropriate in the circumstances, including withdrawing accreditation and ordering it to cease operation. If the Committee is of the opinion that the facility is unsafe, it must request the Registrar to notify the public of the deficiencies and prohibit registrants from using the facility.

18.3. Where a facility is no longer providing patient services, the Committee may withdraw the facility's accreditation.

18.4. Council may withdraw accreditation in accordance with the RHPA.

Article 19 – Approved Procedures

19.1. Each certificate of accreditation must include a schedule listing the procedures which have been approved for the facility, and the names of the registrants who have been given privileges to perform the procedures at the facility.

19.2. The schedule of procedures may be amended from time to time upon the application of the facility and the approval of the Committee.

19.3. Only those procedures which are approved by the Committee and set out in the schedule to the facility's certificate of accreditation may be performed in the facility.

19.4. Where a facility is no longer being used for the procedures set out in Article 13, the Medical Director must inform the Assistant Registrar. The Committee may withdraw the facility's certificate of accreditation.

Article 20 – Health Authority Agreement

20.1. Every facility must have a written agreement with a health authority pursuant to which the health authority agrees to provide emergency treatment if a patient has to be transferred from the facility.

Article 21 – Privileges

21.1. A registrant must have privileges at an accredited facility prior to performing any of the services and procedures listed in Part B;

21.2. The Medical Director must only grant and renew privileges for a registrant to perform procedures in an accredited facility if the Medical Director is satisfied that:
- 21.2.1. the applicant is a suitable and competent candidate
- 21.2.2. the treatment services and procedures are within the privileges requested and within the knowledge, skill, and judgment of the applicant and
- 21.2.3. those privileges are the same as granted by Shared Health or a Regional Health Authority or are recommended through the Shared Health credentialing process and those privileges are and remain in good standing.

21.3. Where the registrant does not have Shared Health or Regional Health Authority privileges the Medical Director must only provide privileges for a specific facility if the Committee has already granted privileges under the following process:
- 21.3.1. utilize the established Shared Health credentialing process to assess applicants using established specialty groups;
- 21.3.2. implement a non-refundable assessment fee paid to Shared Health or the Regional Health Authority payable by the registrant seeking credentials for the credentialing process;
- 21.3.3. seek and obtain an assessment from Shared Health regarding the granting of privileges; and then
- 21.3.4. the Committee shall decide whether to grant privileges.

21.4. Within 15 calendar days of granting or renewing privileges the Medical Director must provide the Assistant Registrar with the particulars of the privileges granted in the facility.

21.5. Any registrant who performs services and procedures without obtaining privileges in the facility and any Medical Director who permits a registrant to perform services and procedures without privileges in the facility may be found guilty of professional misconduct.

Article 22 – Standard of Care

22.1. An accredited facility and those registrants performing procedures must meet appropriate standards for the quality and safety of those treatments and procedures performed in that facility. To receive and maintain accredited status, a facility must:
- 22.1.1. demonstrate compliance with appropriate standards for quality and safety of treatments and procedures performed;

22.1.2. provide patient care in a manner consistent with good medical care as defined in the CPSM Standards of Practice Regulation and elaborated on in the Standards of Practice, Practice Directions, and Code of Ethics and Professionalism; and

22.1.3. engage in ongoing processes of self-review and quality improvement.

Article 23 – Patient Care

23.1. Anaesthetic Care

23.1.1. All patients proposed to undergo anaesthesia in a facility must be assigned an American Society of Anaesthesia risk score and only patients with ASA I, II and III Risk scores may have a procedure performed unless otherwise indicated in the accreditation approval.

23.1.2. General anaesthesia must not be given to infants under the age of twenty-four months.

23.1.3. A patient who receives general anaesthesia or procedural sedation should only leave the facility in the care of an adult.

23.1.4. Procedural sedation must be administered by or under the direct supervision of a registrant with appropriate training acceptable to CPSM to provide procedural sedation.

23.1.5. A patient who receives procedural sedation must be attended by a registered nurse or a registrant who is not assisting in the surgical procedure and who is trained to monitor patients under procedural sedation.

23.1.6. There must be at least two personnel who are certified in basic cardiopulmonary resuscitation within the facility while patients are receiving care.

23.1.7. All equipment for the administration of anaesthetics must be readily available, clean and properly maintained.

23.2. A registrant who has been granted privileges must:

23.2.1. be in the room at all material times during the performance of a procedure in the facility.

23.2.2. ensure that following any procedure, patients receive an adequate recovery period under supervision before leaving the facility.

23.2.3. be responsible for the post-operative care of the patient within the facility.

23.2.4. ensure qualified support staff are on duty during and after a procedure in the facility.

23.2.5. maintain accurate information concerning the medical condition of patients in a clinical record which meets the expected standards of medical record-keeping, including documentation related to the informed consent of the patient for the procedure(s) performed in a facility.

23.2.6. perform procedures in a facility only if the facility is adequately equipped and has maintained operating and post-operative rooms and all equipment is safe, well maintained and compliant with applicable federal, provincial, and municipal legislation.

23.3. A registrant shall not perform a procedure in an accredited facility unless the procedure is one that should safely allow the discharge of a patient from medical care in the facility within 23 hours of the day cycle (no overnight).

Article 24 – Infection Control

24.1 A facility must:
- 24.1.1 use sterilization techniques,
- 24.1.2 store medical and dental supplies, and
- 24.1.3 use waste handling and disposal procedures

consistent with the standards applicable to hospitals.

24.2 A facility must comply with all guidelines CPSM may require the facility to comply with to meet best practices on infection control practices in a facility setting, including the Ontario Public Health Infection Prevention and Control for Clinical Office Practice.

Article 25 – Medical Director

25.1 The facility shall appoint a medical director, who is a registrant acceptable to the Committee, and who must:
- 25.1.1 enforce the standards of care in the facility, which include the safe and effective care of patients in the facility;
- 25.1.2 be responsible for the administration of the facility; and
- 25.1.3 provide required reporting to CPSM.

25.2 In enforcing the standards of care in the facility which includes the safe and effective care of patients, the medical director must ensure that:
- 25.2.1 procedures and equipment are appropriate and safe;
- 25.2.2 procedures are performed in accordance with current good medical care and practice;
- 25.2.3 sufficient numbers of appropriately trained personnel are present during procedures;
- 25.2.4 procedures approved by the Committee as set out in the certificate of accreditation are only performed at the facility by registrants with privileges;
- 25.2.5 persons who provide services to the facility have appropriate qualifications and maintain competence to perform the procedures for which the facility is accredited;
- 25.2.6 registrants with privileges have current basic life support skills and other skills appropriate to the clinical settings (such as advanced cardiac support, pediatric advanced life support, and airway management skills);

25.2.7 all direct patient care personnel have life support skills and there must be two such qualified personnel present at any time patients are receiving care;

25.2.8 adequate quality assurance and improvement programs, including the monitoring of infection and medical complication rates, are in place.

25.3 In being responsible for the administration of the facility, the medical director must:

25.3.1 have access to all records and documents relating to the operation of the facility and the procedures performed therein;

25.3.2 develop appropriate and up-to-date policy and procedure manuals, including acceptable staff health policies;

25.3.3 ensure the duties and responsibilities of all personnel are written and understood;

25.3.4 ensure complete and accurate confidential patient records and documentation relating to the operation of the facility and procedures performed are kept current and up to date;

25.3.5 ensure the requirements for granting privileges are met with necessary approvals and complete records kept of all registrants who obtain privileges at the facility, including their applications;

25.3.6 ensure documentation, fees and a complete reporting of all required information to CPSM is submitted when and as required;

25.3.7 meet annually with each registrant who has privileges to review those privileges and document the review; and

25.3.8 attend at the facility at least one day per month or more if prescribed by the Committee to inspect the facility, and meet with other staff to review operations, the facility, standards, and quality assurance;

25.4 In providing required reporting to CPSM, the medical director must:

25.4.1 Ensure that the Assistant Registrar is notified within one working day of becoming aware of any of the following circumstances and provide a report within two weeks of any of the following:

25.4.1.i death that occurs within 10 days of the procedure;

25.4.1.ii transfers from the facility to a hospital regardless of whether or not the patient was admitted;

25.4.1.iii unexpected admission to hospital within 10 days of a procedure performed;

25.4.1.iv clusters of infections among patients treated in the facility; or

25.4.1.v procedure performed on wrong patient, side, or site or wrong procedure; or

25.4.1.vi any other major adverse patient outcome.

25.4.2 notify the Assistant Registrar of any change in ownership of the facility within one month;

25.4.3 promptly notify the Assistant Registrar if the facility is no longer providing patient services within one month;

25.4.4 promptly notify the Assistant Registrar if there is a major change in equipment or renovations to the facility or the accredited list of procedures within ten days; and

25.4.5 advise the Assistant Registrar of resignation, revocation, suspension, or restriction of privileges of staff immediately.

Article 26 – Audit and Quality Control

26.1 All certificates of accreditation are subject to the following conditions:

26.1.1 all procedures and all clinical records must comply with the requirements of standards of care set by CPSM.

26.1.2 quality assurance and improvement programs are in place sufficient to demonstrate that standards of care set by CPSM and required for good medical care are met in the facility.

Article 27 – Annual Report

27.1. The medical director must review the facility's quality assurance and improvement programs at least annually.

27.2. Within 30 days of each calendar year end, the medical director must forward an annual report in the prescribed form to the Assistant Registrar outlining:

27.2.1 the exact number and types of procedures performed in the facility;

27.2.2 the exact number and type of adverse outcomes and events, including infections and complications, arising from procedures done in the facility;

27.2.3 exact number of events such as needlestick, incomplete sterilization, breaks in technique, medication errors, each of which must be investigated and documented;

27.2.4 assurance that quality assurance and quality improvement program initiatives in the facility sufficient to demonstrate the standards of care set by CPSM and required for good medical care;

27.2.5 the number of transfers to hospital from the facility

27.2.6 list of registrants with privileges and health care staff

27.2.7 List of registrants whose privileges were not renewed, or suspended, or revoked with details;

27.3. Included with the annual report, the medical director must review, sign, and return to the Assistant Registrar an annual declaration in a form prescribed by the Committee confirming that they are aware of their responsibilities as set out in law, this Bylaw, Standards of Practice, and Practice Directions.

Article 28 – Inspections and Audits

28.1. At any time and without notice, a facility is subject to inspection and audits by registrants or other persons with expertise (the latter designated by the Assistant Registrar) to conduct inspections and audits, including, but not limited to if there is:
- 28.1.1. a change in or addition to procedures offered at the facility;
- 28.1.2. renovations in the facility;
- 28.1.3. an adverse patient outcome;
- 28.1.4. a possible failure to comply with this Bylaw or the approval accreditation;
- 28.1.5. a possible failure to meet appropriate standards;
- 28.1.6. a possible risk to patient care and safety.

28.2. The facility will be required to pay the costs of any such inspection/audit and any required follow-up expenses.

28.3. If access to the facility for any inspection is refused, the Committee may take such action it deems necessary including, suspending, revoking or amending the facility's certificate of accreditation.

28.4. The Committee may appoint an investigator with powers under s. 183(6) of the RHPA.

Article 29 – Appeal

29.1 The facility or a registrant may appeal any decision of the Committee to the Executive Committee pursuant to sections 183 and 38 of the RHPA by filing a written notice of appeal with the Registrar within thirty calendar days of being informed of the decision. The notice of appeal must specify the reasons for the appeal.

Article 30 – Administration Fees for Facilities

30.1 The facility shall pay all expenses, charges and fees incurred by CPSM in respect of the accreditation or inspection of the facility and the administration of Part B of this Bylaw.

Article 31 – Transition

31.1 All accreditations and approvals of facilities, procedures, medical directors, conditions, and privileges granted at the time this Bylaw comes into force continues to be valid.

31.2 To permit the orderly accreditation of new facilities under Article 14 effective the date of the Annual General Meeting, June 9, 2021, registrants must not perform these procedures at a facility unless the facility:

31.2.1 has applied for accreditation by December 1, 2021,

31.2.2 has been granted at least conditional or full accreditation by December 1, 2022,

31.2.3 is actively working on obtaining full accreditation as determined by the Committee, and

31.2.4 is seeking to comply with all requirements of this Part of the Bylaw as if it were a fully accredited facility.

31.3 The Committee may determine whether the facility is compliant with the provisions in 31.2.3 and 31.2.4.

NOTE – The list for additional procedures for section 13.3 is on the next page.

Further Procedures to be Performed in an Accredited Non-Hospital Medical or Surgical Facility

Further Procedures to be Performed in an Accredited Non-Hospital Medical or Surgical Facility

1. Procedures that have a sufficient risk of potential harm to the patient require accreditation to be performed in a non-hospital medical or surgical facility (if not performed in a hospital) as per the Accredited Facilities Bylaw to section 13.2

2. The criteria for assessing sufficient risk of potential harm to a patient include:
   - Level of anaesthesia and/or sedation
   - Need for medical device reprocessing (infection risk)
   - Complexity of procedure and risk of complications.

3. The Program Review Committee has the authority to direct any further procedures which must be performed in an accredited facility in order to meet the minimum acceptable standard of care for that procedure. Program Review Committee has directed the following procedures be performed in an accredited facility:
   a) Intravenous ketamine administration.